Message

From: Brown, Amy [Amy.Brown@fdacs.gov]
Sent: 6/1/2020 1:28:47 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Dominy, Randy [Dominy.Randy@epa.gov]; Friend, Kelly [Kelly.Friend@fdacs.gov]; Singh, Rashmi [Rashmi.Singh@fdacs.gov]; Cooper, James [James.Cooper@fdacs.gov]; Damessous, Lee [Lee.Damessous@fdacs.gov]; Conti, Lisa [Lisa.Conti@fdacs.gov]; Tannenbaum, Deborah [Deborah.Tannenbaum@fdacs.gov]; Frazier, Courtney [Courtney.Frazier@fdacs.gov]
CC: McNally, Robert [Mcnally.Robert@epa.gov]; Overstreet, Anne [overstreet.anne@epa.gov]; Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Reynolds, Alan [Reynolds.Alan@epa.gov]
Subject: RE: Follow Up to FDACs Briefing - Pesticide Program Update: EPA Approves Experimental Use Permit to Test Innovative Biopesticide Tool to Better Protect Public Health
Attachments: ATT00001.txt

Thank you so much Mike and team!

Amy

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From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Monday, June 1, 2020 9:24 AM
To: Dominy, Randy <Dominy.Randy@epa.gov>; Friend, Kelly <Kelly.Friend@fdacs.gov>; Brown, Amy <Amy.Brown@fdacs.gov>; Singh, Rashmi <Rashmi.Singh@fdacs.gov>; Cooper, James <James.Cooper@fdacs.gov>; Damessous, Lee <Lee.Damessous@fdacs.gov>; Conti, Lisa <Lisa.Conti@fdacs.gov>; Tannenbaum, Deborah <Deborah.Tannenbaum@fdacs.gov>; Frazier, Courtney <Courtney.Frazier@fdacs.gov>
Cc: McNally, Robert <Mcnally.Robert@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: Follow Up to FDACs Briefing - Pesticide Program Update: EPA Approves Experimental Use Permit to Test Innovative Biopesticide Tool to Better Protect Public Health

Listed below is the OPP Update I mentioned at last week's briefing on Oxitec's EUP. The update contains a link to the docket which now includes EPA's risk assessment "Human Health and Environmental Risk Assessment for the New Product OX5034 Containing the Tetracycline Repressible Transactivator Protein Variant (tTAV-OX5034; New Active Ingredient) Protein, a DsRed2 Protein Variant (DsRed2-OX5034; New Inert Ingredient) and the Genetic Material (Vector pOX5034) Necessary for Their Production in OX5034 *Aedes aegypti,*" (docket ID: EPA-HQ-OPP-2019-0274-0359).

Once I receive the authorization to send the Power Point of our presentation, I will send.

Best Regards,

Mike Mendelsohn, Chief
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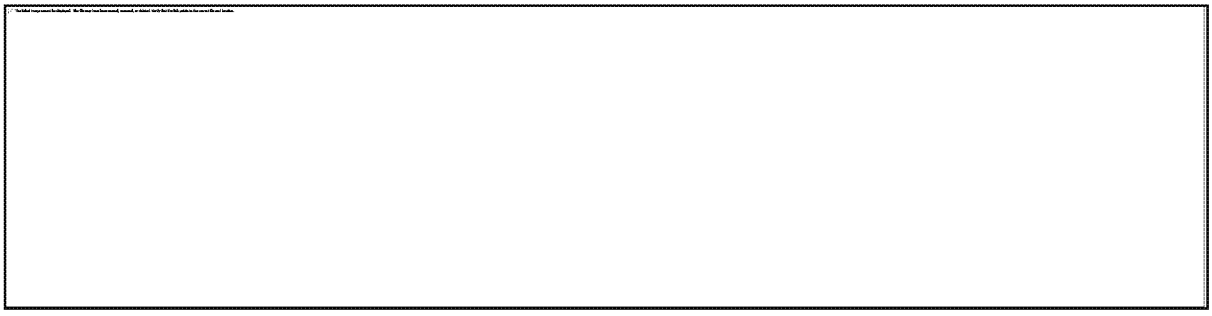
From: U.S. EPA Office of Chemical Safety and Pollution Prevention <oppt.epa@public.govdelivery.com>
Sent: Friday, May 01, 2020 2:29 PM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: Pesticide Program Update: EPA Approves Experimental Use Permit to Test Innovative Biopesticide Tool to Better Protect Public Health



EPA Approves Experimental Use Permit to Test Innovative Biopesticide Tool to Better Protect Public Health

Today, after extensive evaluation of the best available science and public input, the U.S. Environmental Protection Agency (EPA) has granted an experimental use permit (EUP) to Oxitec Ltd. to field test the use of genetically engineered *Aedes aegypti* mosquitoes as a way to reduce mosquito populations to protect public health from mosquito-borne illnesses.

To meet today's public health challenges head-on, the nation needs to facilitate innovation and advance the science around new tools and approaches to better protect the health of all Americans. After all appropriate approvals are garnered, EPA looks forward to receiving field test results regarding the effectiveness of this promising new tool that could help combat the spread of mosquito-borne diseases like the Zika virus.

The EUP is designed to test the effectiveness of genetically engineered *Aedes aegypti* mosquitoes as a way to reduce mosquito populations in a controlled environment with appropriate

safeguards as a first step to potentially wider use in the United States. The company must receive state and local approval before proceeding with field testing.

Oxitec's carefully developed field tests will be conducted, if approved by state and local authorities, over a two-year period in Monroe County, Florida, beginning in summer 2020, and in Harris County, Texas, beginning in 2021.

During these field tests, Oxitec will release into the environment male mosquitoes genetically modified to carry a protein that will inhibit the survival of their female offspring when they mate with wild female mosquitoes. The male offspring will survive to become fully functional adults with the same genetic modification, providing multi-generational effectiveness that could ultimately lead to a reduction in *Aedes aegypti* mosquito populations in the release areas. EPA anticipates that this could be an effective tool to combat the spread of certain mosquito-borne diseases like the Zika virus in light of growing resistance to current insecticides.

Since only male mosquitoes will be released into the environment and they do not bite people, they will not pose a risk to people. It is also anticipated that there would be no adverse effects to animals such as bats and fish in the environment.

Oxitec is required to monitor and sample the mosquito population weekly in the treatment areas to determine how well the product works for mosquito control and to confirm that the modified genetic traits disappear from the male *Aedes aegypti* mosquito population over time. EPA has also maintained the right to cancel the EUP at any point during the 24-month period if unforeseen outcomes occur.

EPA's decision and the approved permit are available in Regulations.gov in Docket ID EPA-HQ-OPP-2019-0274.